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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,689	02/26/2002	Akio Wakabayashi	AKIOWAK.004A	6414

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EXAMINER

PANTUCK, BRADFORD C

ART UNIT PAPER NUMBER

3731

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/084,689

Applicant(s)

WAKABAYASHI, AKIO

Examiner

Bradford C Pantuck

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/10/2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 3 and 14-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-13, 29, and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>06-06-2002</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims 1-13, 29, and 30 in the reply filed on May 15, 2004 is acknowledged. The traversal is on the ground(s) that the search required for the elected claims would be the same search required for the other claims. This is not found persuasive because the search required for the non-elected claims would be a different and more extensive search into additional subclasses.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 14-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected groups, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 15, 2004.

3. In a telephone interview on September 7, 2004, Examiner spoke with Attorney Douglas G. Muehlhauser who further elected Species A [Figures 2B-2D] of Group I, *as required in the Election/Restriction requirement dated April 5, 2004.*

Consequently, claim 3 is withdrawn as being drawn to a nonelected species.

Therefore, Claims 1, 2, 4-13, 29, and 30 have been examined in this Office Action.

Drawings

4. Figures 1A-1C should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled

“Replacement Sheet” in the page header (as per 37 CFR 1.121(d)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 2, 4, 6, and 8-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Publication No. US 2001/0016747 A1 to Romano et al. Regarding Claims 1, 2, 4, 6, and 8, Romano discloses a suturing device (40) having a sheath (42) with a distal end (52) capable of entering/puncturing soft tissue when moved distally {para. [0042]; Fig. 30}. The suture is grasped by the distal end of member (44) at socket (90), and so member (44) can be considered a handle—a component used to grip suture (46) {para. [0046]; Fig. 15}. Alternatively, with reference to Fig. 19, proximal end (92) of suture (46) can be considered a “handle” because one could use component (92) to hold onto the rest of the suture. “Finger notch 62” is the sheath handle of Romano’s device {para. [0043]; Fig. 30}. Comparing Fig. 30 to Fig. 31, it is evident that suture (56) slides inside of sheath (42). Suture (46) has a J-shaped

hook at its distal end, when the suture is in its natural (unconstrained) position {para. [0046]; Fig. 19}.

With regards to member (46) being a suture: Wire (46) is made of a shape memory metal, and therefore meets the definition of a suture—generally a long, flexible, thin member—and specifically described in Applicant's specification at page 9 in the first full paragraph. Thus, although member (46) is described by Romano as being a "suture passer" or "delivery/retrieving wire component," it *meets all of the structural limitations* as set forth by Applicant.

Because the hook (94) of suture (46) takes the shape as shown in Fig. 19, upon deployment, the hook will resist movement back into distal end (52) of sheath (42). The member (46) will certainly be capable of sliding back into the sheath, but because of its resiliency, the user/member (60) will have to apply enough force to straighten member (94) to allow it to re-enter the lumen of sheath (42).

6. Regarding Claims 9 and 10, members (60) and (64) are suture applicators, which move suture handle (44) proximally and distally relative to the suture sheath handle (62) [Fig. 30]. The applicator is capable and meant to fit in one hand of the user.
7. Regarding Claim 11, the applicator expels suture hook (94) relative to a surgical field such as the skin of a patient.
8. Regarding Claim 12, flange (52) is capable of regulating the depth of penetration of the machine into tissue.
9. Regarding Claim 13, lock (70/72) will be locked when applicator (60/64) is depressed distally [Fig. 30].

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 2, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,613,975 to Christy. Christy discloses a sheath (20), with an exterior surface that can be gripped by the user. A surface that can be gripped is considered a "handle." Christy discloses a suture (50) having a suture handle (90/906) is at the proximal end of the suture and can move the suture within the sheath [Column 5, lines 54-67]. Christy discloses a suture hook (30), which is at the proximal and distal ends of the suture (the suture is threaded all the way through hook (30). The hook is first located within the sheath [Fig. 7B] and then expelled from the sheath [Fig. 7C], thus to resist going back into the sheath. It is possible to use suture handle (90/906) for this purpose, although it is not necessarily intended for such a purpose. The hook (30) is attachable and detachable from the suture—that is the suture can be tied (or otherwise attached to the needle 30) to the needle and then untied.

11. Claims 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,499,991 to Garman et al. Garman discloses a tool for suturing body tissue (capable of being used with arteries) comprising a tubular body (14) with a sharpened distal end (18) for cutting through tissue when it is rotated. Garman discloses a hook (34) exiting distal end of the tubular body (14) at guide channel (20) to hold onto severed tissue [Column 3, line 57 to Column 4 line 5; Fig. 3].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,613,975 to Christy in view of Publication No. US 2003/0078600 A1 to O'Quinn et al. Christy discloses all of the claimed subject matter, but fails to disclose a braided suture. O'Quinn discloses a similar surgical suturing machine and employs braided suture, rather than the assumedly monofilament suture of Christy. Braiding produces a stronger suture/rope/string, as is well known: "a cord of three strands is not quickly broken" [Ecclesiastes 4:12]. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use braided suture instead of monofilament suture in order to have stronger suture and thus prevent a wound from opening up before the surgeon intends.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,643,292 to Hart

Publication No. US 2002/0007130 A1 to Burbank et al.

Publication No. US 2003/0163147 A1 to Rabiner et al.

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U.S. Patent No. 5,919,207 to Taheri

Publication No. US 2004/0092975 A1 to Loshakove, et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (703) 308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP

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September 14, 2004

AN
ANHTUAN T. NGUYEN
PRIMARY EXAMINER

9/15/04.